

K970954

JUN 10 1997

Appendices

Appendix A - 510(k) Summary

Device Name	Trade name :o.b.® Applicator Tampon Classification name: unscented menstrual tampon
Equivalence to legally marketed device	The modified o.b.® Applicator Tampon is substantially equivalent to the current commercial o.b.® Applicator Tampon.
Device description	<p>o.b.® Applicator Tampons are used to absorb menstrual fluid or other vaginal discharge. These tampons will be available in regular, super and super plus absorbencies.</p> <p>o.b.® Applicator Tampons are made of cotton and rayon, a polyethylene/polyester cover, and cotton or rayon string.</p> <p>The applicator consists of a cardboard laminate with a coating.</p>
Intended use	o.b.® Applicator Tampons are inserted into the vagina to collect menstrual fluid. This is the same intended use as current commercial tampons.
Technological characteristics	<p>The only difference between the modified applicator tampon and the predicate device is the composition of the coating on the applicator. All other technological characteristics are the same for the modified and the predicate device.</p> <p>There is no impact on the function of the device because of the change in applicator coating.</p>

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Performance data Non-clinical testing	Biocompatibility and microbiological testing were conducted on extracts of the coated applicator. The results of these tests demonstrate that the modified o.b.® Applicator Tampon is equivalent to legally marketed tampons. The following tests were conducted: <ul style="list-style-type: none">• Cytotoxicity• Vaginal Irritation in Rabbits• Microbiological testing
Performance data Clinical testing	A Repeat Insult Patch Test was conducted to confirm the lack of the potential for human dermal irritation and sensitization.
Conclusion	Results of non-clinical and clinical testing indicate that the safety of modified applicator is comparable to current legally marketed, commercial applicator tampons.
Contact	Submitted by Personal Products Company 199 Grandview Road Skillman, NJ, 08558-9418 Contact person: Ralph A. Petrone Manager, Regulatory Affairs J&J Consumer Franchises Worldwide 908 874 1214
Date	This Summary was prepared on February 21, 1997



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 10 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ralph Petrone
Manager, Regulatory Affairs
Johnson & Johnson
Consumer Franchises Worldwide
199 Grandview Road
Skillman, New Jersey 08558-9418

Re: K970954
o.b. Applicator Tampon
Dated: April 17, 1997
Received: April 21, 1997
Regulatory class: II
21 CFR §884.5470/Product code: 85 HEB

Dear Mr. Petrone:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K970954

Device Name: o.b. applicator tampon

Indications for Use:

*
o.b. applicator tampons are used to absorb menstrual fluid or other vaginal discharge.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓

Robert D. Anthony
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

(Optional Format 1-2-96)

510(k) Number K970954